510(k) Summary of Safety and Effectiveness K132972

Date Prepared:	**October 25, 2013**
Applicant:	Medtronic, Inc. Medtronic Perfusion Systems 7611 Northland Drive Minneapolis, MN 55428 **Establish Registration Number:** 2184009
Contact Person:	Julia A. Nelson Principal Regulatory Affairs Specialist Phone: (763) 514-9844 Fax: (763) 367-8361 E-mail:julia.a.nelson@medtronic.com
Trade Name:	Affinity Fusion® Cardiotomy/Venous Reservoir with Balance® Biosurface
Common Name:	Cardiotomy Venous Reservoir
Classification Name:	Cardiopulmonary bypass blood reservoir
Classification:	Class II, 21 870.4400
Product Code:	DTN
Name of Predicate Device:	Affinity Fusion® Cardiotomy/Venous Reservoir with Balance® Biosurface (K122914)
Reference Device:	Affinity® NT Cardiotomy/Venous Reservoir with Filter Model 540 (K936003)

OCT 28 2013

Device Description:

The Affinity Fusion® Cardiotomy/Venous Reservoir (CVR) with Balance® Biosurface is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to 6 hours in duration. The CVR is also intended for use during vacuum assisted venous drainage (VAVD) procedures.

The Affinity Fusion Cardiotomy/Venous Reservoir with Balance Biosurface is also intended for use after open heart surgery to collect autologous blood from the chest and to aseptically return the blood to the patient for blood volume replacement. The inside of the jar is coated with Balance Biosurface to reduce platelet activation and adhesion and preserve platelet function.

This product is single-use, nontoxic, nonpyrogenic, supplied STERILE in individual packaging. The Affinity Fusion Cardiotomy/Venous Reservoir is sterilized by ethylene oxide.

Intended Use:

The Affinity Fusion Cardiotomy/Venous Reservoir with Balance Biosurface is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to 6 hours in duration. The CVR is also intended for use during vacuum assisted venous drainage (VAVD) procedures.

The Affinity Fusion Cardiotomy/Venous Reservoir with Balance Biosurface is also intended for use after open heart surgery to collect autologous blood from the chest and to aseptically return the blood to the patient for blood volume replacement.

Contraindications:

Do not use this device for any purpose other than indicated.

Do not use if air leaks are observed during priming and/or operation; this may result in air embolism to the patient and/or fluid loss.

The Affinity Fusion Cardiotomy/Venous Reservoir is contraindicated for use in postoperative chest drainage and autotransfusion procedures when:

- There is an air leak in the lung or gross perforations to the chest wall exist.
- Pericardial, mediastinal, pulmonary or systemic infection or malignancy is present.
- Gross contamination or a lymphatic failure is present or suspected.
- Suctioned blood is obtained from a site where a topical hemostatic agent has been used.
- The chest is open and vacuum is applied.
- Protamine has been administered prior to the reservoir being removed from the bypass circuit.
- The patient is returned to surgery for any reason.
- Vented chest tubes not incorporating vent flow regulation, such as a stopcock, are used.
  Caution: An assessment should be made of the quality and suitability of the blood that has been collected before re-infusion begins.

Comparison to Predicate Devices:

A comparison of the Affinity Fusion® Cardiotomy/Venous Reservoir with Balance® Biosurface to the predicate device (the Affinity Fusion® Cardiotomy/Venous Reservoir with Balance® Biosurface) indicates the following similarities:

- Intended Use: The intended use is the same as predicate and reference devices.
- Design: The basic design is the same as the predicate. Minor enhancements were made to the cardiotomy filtration, and a valve protector was added.

- Materials: The materials are the same as the predicate, with the exception of the cardiotomy filtration media, which is the same as the reference device.
- Principles of Operation and Technology: The principles of operation are the same as the predicate device.
- Performance: The performance is substantially equivalent to the predicate and/or reference device.

Summary of Performance Data

The following verification and validation testing has demonstrated that substantially equivalent to the predicate device.

	Test Performed	Result
Testing per Special Controls Guidance Document	Blood Damage Testing	Pass
	Defoaming	Pass
	Filtration Efficiency	Pass
Additional Testing	Cardiotomy Gaseous Microemboli	Pass
	Dynamic Holdup	Pass
	Prime Breakthrough	Pass
	Static Holdup	Pass
	Volume Marking Accuracy	Pass
	Reservoir Capacity	Pass
	Particulate Count	Pass

A complete biocompatibility assessment was conducted based on ISO 10993-1. The following biocompatibility testing was performed related to new material and design change to the subject device.

Test Performed	Result
Cytotoxicity	Pass
Hemocompatibility	Pass

Clinical testing was not required to establish substantial equivalence with the predicate devices.

Conclusion:

The data included in this submission is sufficient to provide reasonable assurance of the safety and effectiveness of the device and the Affinity Fusion® Cardiotomy/Venous Reservoir with Balance® Biosurface is substantially equivalent to the legally marketed predicate device, the Affinity Fusion® Cardiotomy/Venous Reservoir with Balance® Biosurface (K122914).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-002

October 28, 2013

Medtronic, Inc.
Julia Nelson
Principal Regulatory Affairs Specialist
Medtronic CardioVascular
8200 Coral Street NE
Mailstop MVS83
Mounds View, MN 55112

Re: K132972
Trade/Device Name: Affinity Fusion® Cardiotomy/Venous Reservoir (CVR) with Balance®
Regulation Number: 21 CFR 870.4400
Regulation Name: Cardiopulmonary Bypass Blood Reservoir
Regulatory Class: Class II
Product Code: DTN
Dated: September 19, 2013
Received: September 23, 2013

Dear Ms. Nelson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: December 31, 2013
See PRA Statement on last page.

510(k) Number *(if known)*
K132972

Device Name
Affinity Fusion® Cardiotomy/Venous Reservoir with Balance® Biosurface

Indications for Use *(Describe)*

The Affinity Fusion Cardiotomy/Venous Reservoir with Balance Biosurface is intended to be used in an extracorporeal perfusion circuit to collect venous and cardiotomy suctioned blood during routine cardiopulmonary procedures up to 6 hours in duration. The CVR is also intended for use during vacuum assisted venous drainage (VAVD) procedures.

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Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*